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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,247	09/25/2001	David A. Ferrick	A-66038-1/RMS/DLR	9693
959	7590	07/27/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP.			MURPHY, JOSEPH F	
28 STATE STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02109			1646	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/963,247	Applicant(s) FERRICK ET AL.	
	Examiner Joseph F Murphy	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,17,19-21 and 30-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-17, 19-21, 30-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

Claims 16-17, 19-21, 30-42 are pending and under consideration.

Response to Amendment

The rejection of claims 16-17, 19-22, 30-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 16-17, 19-22, 30-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been obviated by Applicant's amendment and is thus withdrawn.

New issues are set forth below.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-17, 19-21, 30-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for a bioactive agent that modulates IgE production, said method comprising: a) contacting, under conditions permissive for expression of an IgE fusion protein, a candidate bioactive agent and a cell, said cell comprising a genome which has been modified to express an IgE fusion protein under the control of an IgE promoter, said IgE promoter having the sequence of SEQ ID NO: 1, said IgE fusion

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protein comprising: i) an E heavy chain; and ii) a fluorescent protein, and b) determining the amount of said IgE fusion protein ' expressed by said cell; wherein a difference in the amount of said IgE fusion protein expressed in the absence of said candidate agent as compared to the amount expressed in the absence of said candidate agent indicates that said agent modulates IgE production, does not reasonably provide enablement for a method of screening for a bioactive agent that modulates IgE production, said method comprising: a) contacting, under conditions permissive for expression of an IgE fusion protein, a candidate bioactive agent and a cell, said cell comprising a genome which has been modified to express an ICE fusion protein under the control of an ICE promoter, said IgE fusion protein comprising: i) an E heavy chain; and ii) a fluorescent protein, and b) determining the amount of said IgE fusion protein ' expressed by said cell; wherein a difference in the amount of said IgE fusion protein expressed in the absence of said candidate agent as compared to the amount expressed in the absence of said candidate agent indicates that said agent modulates IgE production. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to methods of screening using a construct comprising an IgE promoter, an ϵ heavy chain and a reporter gene. Claims 16-17, 19-21, 30-42 are overly broad since insufficient guidance is provided as to which of the myriad of possible nucleic acid sequences serve as IgE promoters, and Applicant only discloses an IL-4 inducible epsilon promoter of SEQ ID NO: 1. Since the claims encompass variant nucleic acids, it would require undue experimentation to make and use the claimed invention. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary,

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but whether, if experimentation is necessary, it is undue. Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass polynucleotides that the specification only teaches one skilled in the art to test for functional variants. It would require undue experimentation for one of skill in the art to practice the claimed method, since the skilled artisan would have to first make the polynucleotide variants, but there is no functional limitation set forth for the polynucleotide variant. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to practice the claimed invention in its full scope.

Claims 16-17, 19-21, 30-42 are rejected under 35 U.S.C. 112, first paragraph, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in paper NO. 10, 9/26, 2002. Applicant is directed to the Guidelines

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for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. The claims are directed to methods of screening using a construct comprising an IgE promoter, an ϵ heavy chain and a reporter gene, while Applicant only discloses an IL-4 inducible epsilon promoter of SEQ ID NO: 1. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of substitutions, deletions, insertions and/or additions that may be made to the promoter. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid with a sequence as set forth in SEQ ID NO: 1 is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

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Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
July 15, 2004